UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,899	01/09/2001	Franciscus Antonius, M. Redegeld	4692US	1305

24247 7590 07/06/2004

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/756,899	REDEGELD ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 10, 33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 10, 33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 10, 33 and 34 are pending.

2. In view of the amendment filed 4/29/04, the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) a pharmaceutical composition consisting of a peptide consisting of SEQ ID NO: 1 and a pharmaceutically acceptable carrier or excipient for treating bronchial constriction, **does not** reasonably provide enablement for *any* pharmaceutical composition consisting of a peptide of SEQ ID NO: 1 and a pharmaceutically acceptable carrier or excipient for treating any disease state as set forth in claims 1, 10, 33 and 34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a pharmaceutical composition consisting of a peptide consisting of SEQ ID NO: 1 and a pharmaceutically acceptable carrier or excipient for treating bronchial constriction wherein the peptide is present in an amount of 200 micrograms. The specification discloses on page 5 that disease to be treated with the claimed compound includes "asthma, allergy, including contact allergy and occupational allergy, chronic inflammatory bowel

disorders, viral infection and multiple sclerosis. Applicant considers the possibility that migraine is also included in the list of disorders".

The specification does not teach how to use the claimed pharmaceutical composition mentioned above for treating *all* disease state because there is insufficient guidance and in vivo working example demonstrating that the claimed composition could treat all disease state characterized by a serum concentration of free light chain of Ig in serum of at least 8 mg/l, a spinal fluid concentration of free light kappa-chain of Ig of at least 70 mg/l or a spinal fluid concentration of free lambda-chain of Ig of at least 300mg/l.

Redegeld *et al*, of record, teach that free light chain is found in serum of a number of pathological conditions such as autoimmune multiple sclerosis, rheumatoid arthritis, and neurological disorders (See abstract, in particular).

Hoppers *et al* teach that free light chain is found in urine of clinical relapse systemic lupus erythematosus (See abstract, in particular). Given the indefinite number of disease, there is insufficient in vivo working example demonstrating that the claimed pharmaceutical composition is effective for any autoimmune disease.

Rocken *et al* teach that animal experiments must determine whether specific k light chains are involved in T cell-dependent autoimmune diseases such as allergic encephalitis, inflammatory bowel disease, including contact hypersensitivity, psoriasis, rheumatoid arthritis, experimental allergic encephalitis (experimental model for multiple sclerosis).

Van Noort *et al*, of record, teach autoimmune diseases can be species and model-dependent (See entire document, pages 167-168, in particular). It is not clear the reliance on the animal model of BALB/C mice were skin-sensitized using picrychloride (PLC), dinitrofluorobenzene or oxazolone is appropriate for all autoimmune disease encompassed by the claims. It is not clear the reliance of bronchial constriction model is appropriate for autoimmune disease such as multiple sclerosis, and rheumatoid arthritis as taught by Van Noort et al or chronic inflammatory bowel disorders, viral infection, or migraine as asserted by applicant. The specification is silent with respect to whether the claimed pharmaceutical composition could treat autoimmune multiple sclerosis, rheumatoid arthritis, neurological disorders. There is no recognition in the art that the claimed composition could treat any or all autoimmune disease states. As such, further research would be required. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), the court indicates that "a patent is not a hunting license. It is not

a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

Applicants' arguments filed 4/29/04 have been fully considered but are not found persuasive.

Applicants' position is that (1) when a compound or composition claimed, it is not limited by a recited use that would reasonably correlate with the entire scope of that claim. Autoimmune diseases can be antigen specific, and each model has its own characteristics, due to the interaction of the host immune system and the experimental antigen.

However, the specification does not teach how to use the claimed pharmaceutical composition mentioned above for treating *all* disease state because there is insufficient guidance and in vivo working example demonstrating that the claimed composition could treat all disease state characterized by a serum concentration of free light chain of Ig in serum of at least 8 mg/l, a spinal fluid concentration of free light kappa-chain of Ig of at least 70 mg/l or a spinal fluid concentration of free lambda-chain of Ig of at least 300mg/l.

Redegeld *et al*, of record, teach that free light chain is found in serum of a number of pathological conditions such as autoimmune multiple sclerosis, rheumatoid arthritis, neurological disorders (See abstract, in particular).

Hoppers *et al* teach that free light chain is found in urine of clinical relapse systemic lupus erythematosus (See abstract, in particular). Given the indefinite number of disease, there is insufficient in vivo working example demonstrating that the claimed pharmaceutical composition is effective for any autoimmune disease.

Rocken *et al* teach that animal experiments must determine whether specific k light chains are involved in T cell-dependent autoimmune diseases such as allergic encephalitis,

inflammatory bowel disease, including contact hypersensitivity, psoriasis, rheumatoid arthritis, experimental allergic encephalitis (experimental model for multiple sclerosis).

Van Noort *et al*, of record, teach autoimmune diseases can be species and model-dependent (See entire document, pages 167-168, in particular). It is not clear the reliance on the animal model of BALB/C mice were skin-sensitized using picrychloride (PLC), dinitrofluorobenzene or oxazolone is appropriate for all autoimmune disease encompassed by the claims. It is not clear the reliance of bronchial constriction model is appropriate for autoimmune disease such as multiple sclerosis, and rheumatoid arthritis as taught by Van Noort et al or chronic inflammatory bowel disorders, viral infection, or migraine as asserted by applicant. The specification is silent with respect to whether the claimed pharmaceutical composition could treat autoimmune multiple sclerosis, rheumatoid arthritis, neurological disorders. There is no recognition in the art that the claimed composition could treat any or all autoimmune disease states. As such, further research would be required. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), the court indicates that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 10, and 33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Huang *et al* (of record, J Clin Invest 99(4): 732-36, 1997; PTO 1449).

Huang *et al* teaches a pharmaceutical composition consisting of a synthetic peptide AHWSGHCCL which is 100% identical to the claimed SEQ ID NO: 1 and a pharmaceutical carrier such as 7.25 mM buffer (See Table 1, page 733, col. 1, binding analysis and peptide blocking studies, in particular). The reference further teaches that the reference peptide is synthesized at the protein core facility of the University of Alabama and kept lyophilized at –20C until use (See page 732, col. 2, Protein and peptide preparations, in particular). Just prior to lyophilization and after synthesis, the reference peptide is a buffer. The liquid associated with the

reference peptide prior to lyophilization is considered a form of pharmaceutical carrier. Further, the reference peptide is a diluents just prior to adding to the wells of microplates coated with LCs (See page legend of figure 2, in particular). The reference peptide is useful for reducing the binding of the of immunoglobulin light chain to the Tamm and Horsfall protein or THP (See Table 1 mic, IC_{50} mM, in particular). Claims 10 and 33 are included in this rejection because a composition is a composition irrespectively of its intended use. Thus, the reference teachings anticipate the claimed invention.

Applicants' arguments filed 4/29/04 have been fully considered but are not found persuasive.

Applicants' position is that Huang does not disclose a pharmaceutical composition consisting of a peptide of sequence AHWSGHCCL (SEQ ID NO: 1) and a pharmaceutically acceptable carrier or diluents. Using closed "consisting of" language excludes non-pharmaceutically acceptable carriers and excipients, as well as additional elements which would change the properties of the invention. At most, Huang et al. discloses the peptide of SEQ ID NO:1 together with immunoglobulin light chain (LC). LC is not the peptide of SEQ ID NO: 1, nor is it a pharmaceutically acceptable carrier or excipient. Furthermore, inclusion of the immunoglobulin light chain (1g LC) is materially different from the present invention. The presently claimed invention is directed to the peptide of SEQ ID NO:1, which is used to interrupt the binding of the Ig LC to mast cells. Hence, adding more of the Ig LC, which the claimed compound is to interact with and prevent from binding to a mast cell, is contrary to the claimed invention. Because the peptide plus additional Ig LC, as disclosed in Huang et al., is contrary to the claimed invention, the reference is materially different from the claimed compound alone and cannot anticipate the claimed invention. As a result, Huang et al. fails to teach or suggest a pharmaceutical composition consisting of a peptide consisting of an amino acid sequence of SEQ ID NO: 1 and a pharmaceutical carrier or excipient. Because the reference teaches SEQ ID NO: 1 with Ig LC, and Ig LC is precisely what the compound is used to inhibit, the anticipation rejection necessarily fails.

In contrast to applicant's assertion that the peptide plus additional Ig LC as disclosed in Huang et al is contrary to the claimed invention, Huang *et al* teaches a pharmaceutical composition consisting of a synthetic peptide AHWSGHCCL which is 100% identical to the claimed SEQ ID NO: 1 and a pharmaceutical carrier such as 7.25 mM buffer (See Table 1, page 733, col. 1, binding analysis and peptide blocking studies, in particular). The reference further

teaches that the reference peptide is synthesized at the protein core facility of the University of Alabama and kept lyophilized at –20C until use (See page 732, col. 2, Protein and peptide preparations, in particular). Just prior to lyophilization and after synthesis, the reference peptide is a buffer. The liquid associated with the reference peptide prior to lyophilization is considered a form of pharmaceutical carrier. Further, the reference peptide is in diluents or buffer from 0 to 7.25 mM just prior to adding to the wells of microplates coated with LCs (See page legend of figure 2, in particular).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 10, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang *et al* (J Clin Invest 99(4): 732-36, 1997; PTO 1449) in view Gennaro *et al* in Remington's Pharmaceutical Sciences, eighteenth edition, 1990, pages 1300-1329; PTO 892).

Huang *et al* teaches a pharmaceutical composition consisting of a synthetic peptide AHWSGHCCL that is 100% identical to the claimed SEQ ID NO: 1 and a pharmaceutical carrier such as 7.25 mM buffer (See Table 1, page 733, col. 1, binding analysis and peptide blocking studies, in particular). The reference further teaches that the reference peptide is synthesized at the protein core facility of the University of Alabama and kept lyophilized at –20C until use (See page 732, col. 2, Protein and peptide preparations, in particular). Just prior to lyophilization and after synthesis, the reference peptide is a buffer. The liquid associated with the reference peptide

prior to lyophilization is considered a form of pharmaceutical carrier. Further, the reference peptide is in diluents or buffer just prior to adding to the wells of microplates coated with LCs (See page legend of figure 2, in particular). The reference peptide is useful for reducing the binding of the of immunoglobulin light chain to the Tamm and Horsfall protein or THP (See Table 1 mic, IC_{50} mM, in particular). The reference peptide is useful for inhibiting the binding of the of immunoglobulin light chain to the THP (See Table 1 mic, IC_{50} mM, in particular).

The claimed invention differs from the teachings of the reference only in that a pharmaceutical composition consisting of a peptide consisting of an amino acid sequence of SEQ ID NO: 1 and a pharmaceutically acceptable carrier or excipient.

The claimed invention as recited in claim 34 further differs from the teachings of the reference only that the composition wherein the peptide is present in an amount of 200 microgram.

Gennaro *et al* teach various pharmaceutical acceptable carrier or excipient such as purified water, dextrin, or sodium carbonate (See page 1301, page 1321, in particular). Gennaro *et al* teach that pharmaceutical carrier and vehicle are indifferent substances which are useful as solvents for active medicinal and primary importance for diluting and flavoring drugs. Gennaro *et al* teach that the best diluting agent is usually the best solvent for the drug (See page 1300, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the carrier in the pharmaceutical composition consisting of a peptide consisting of AHWSGHCCL that is identical to claimed SEQ ID NO: 1 and a pharmaceutical acceptable carrier as taught by Huang et al for the pharmaceutically acceptable carrier or excipient such as purified water, dextrin, sodium carbonate as taught by Gennaro et al. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Gennaro et al teach that pharmaceutical carrier and vehicle are solvents for active medicinal and primary importance for diluting and flavoring drugs and the best diluting agent is usually the best solvent for the drug (See page 1300, in particular). Huang *et al* teach that the reference peptide is useful for inhibiting the binding of the of immunoglobulin light chain to the THP (See Table 1 mic, IC_{50} mM, in particular). Claims 10 and 33 are included in this rejection because a

composition is a composition irrespectively of its intended use. Claim 34 is included in this rejection because the concentration of peptide such as 200 micrograms is within the purview of one ordinary skill in the pharmaceutical art to adjust the dosage for the particular purpose. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ233; 235 (CCPA 1955). See MPEP § 2144.05 part IIA.

Applicants' arguments filed 4/29/04 have been fully considered but are not found persuasive.

Applicants' position is that Huang et al. does not teach or suggest the claimed invention. Huang et al. discloses the peptide of SEQ ID NO:1 together with Ig LC, which is materially different from the claimed composition. Moreover, Huang et al provides no motivation to make or use the peptide as a pharmaceutical composition. In particular, Huang et al. states that the light chain binding site on THP will help produce strategies that inhibit interaction of LCs with THP..." Huang et al. at page 736, first column). Huang et al. merely suggests a possible future research tool directed at finding inhibitors of the interaction between an LC and THP. Huang et al. does not provide motivation to a person of ordinary skill in the art to make or use a peptide as a pharmaceutical composition to induce an interaction with the LC. Gennaro et al. does not teach or suggest a pharmaceutical comprising the peptide of SEQ ID NO:1 or a composition that interacts with the LC. Therefore, this reference does not supply. The missing elements and does not render the claims obvious in light of Huang et al.

In contrast to applicant's assertion that the peptide plus additional Ig LC as disclosed in Huang et al is contrary to the claimed invention, Huang *et al* teaches a pharmaceutical composition consisting of a synthetic peptide AHWSGHCCL which is 100% identical to the claimed SEQ ID NO: 1 and a pharmaceutical carrier such as 7.25 mM buffer (See Table 1, page 733, col. 1, binding analysis and peptide blocking studies, in particular). The reference further teaches that the reference peptide is synthesized at the protein core facility of the University of Alabama and kept lyophilized at –20C until use (See page 732, col. 2, Protein and peptide preparations, in particular). Just prior to lyophilization and after synthesis, the reference peptide is a buffer. The liquid associated with the reference peptide prior to lyophilization is considered a form of pharmaceutical carrier. Further, the reference peptide is a diluents from 0 to 7.25 mM of buffer just prior to adding to the wells of microplates coated with LCs (See page legend of figure 2, in particular). The claimed invention differs from the teachings of the reference only in that a

pharmaceutical composition consisting of a peptide consisting of an amino acid sequence of SEQ ID NO: 1 and a pharmaceutically acceptable carrier or excipient.

The claimed invention as recited in claim 34 further differs from the teachings of the reference only that the composition wherein the peptide is present in an amount of 200 microgram.

Gennaro *et al* teach various pharmaceutical acceptable carrier or excipient such as purified water, dextrin, or sodium carbonate (See page 1301, page 1321, in particular). Gennaro *et al* teach that pharmaceutical carrier and vehicle are indifferent substances which are useful as solvents for active medicinal and primary importance for diluting and flavoring drugs. Gennaro *et al* teach that the best diluting agent is usually the best solvent for the drug (See page 1300, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the carrier in the pharmaceutical composition consisting of a peptide consisting of AHWSGHCCL that is identical to claimed SEQ ID NO:1 and a pharmaceutical acceptable carrier as taught by Huang et al for the pharmaceutically acceptable carrier or excipient such as purified water, dextrin, sodium carbonate as taught by Gennaro et al. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Gennaro et al teach that pharmaceutical carrier and vehicle are solvents for active medicinal and primary importance for diluting and flavoring drugs and the best diluting agent is usually the best solvent for the drug (See page 1300, in particular). Huang *et al* teach that the reference peptide is useful for inhibiting the binding of the of immunoglobulin light chain to the THP (See Table 1 mic, IC_{50} mM, in particular). Claims 10 and 33 are included in this rejection because a composition is a composition irrespectively of its intended use. Claim 34 is included in this rejection because the concentration of peptide such as 200 micrograms is within the purview of one ordinary skill in the pharmaceutical art to adjust the dosage for the particular purpose. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ233; 235 (CCPA 1955). See MPEP § 2144.05 part IIA.

In contrast to applicant's assertion that there is no motivation to Huang et al provides no motivation to make or use the peptide as a pharmaceutical composition, Huang *et al* teach that the reference peptide is useful for inhibiting the binding of the of immunoglobulin light chain to the THP (See Table 1 mic, IC_{50} mM, in particular). It is noted that none of the claims are method of using the claimed composition. A composition is a composition, irrespective of its intended use.

In response to applicant's argument that Gennaro et al. does not teach or suggest a pharmaceutical comprising the peptide of SEQ ID NO:1 or a composition that interacts with the LC, it is noted that none of pending claims 1, 10, 33 and 34 recite "interacts with the LC". Further, Huang *et al* teaches a pharmaceutical composition consisting of a synthetic peptide AHWSGHCCL which is 100% identical to the claimed SEQ ID NO: 1 and a pharmaceutical carrier such as 7.25 mM buffer (See Table 1, page 733, col. 1, binding analysis and peptide blocking studies, in particular). The reference further teaches that the reference peptide is synthesized at the protein core facility of the University of Alabama and kept lyophilized at –20C until use (See page 732, col. 2, Protein and peptide preparations, in particular). Just prior to lyophilization and after synthesis, the reference peptide is a buffer. The liquid associated with the reference peptide prior to lyophilization is considered a form of pharmaceutical carrier. Further, the reference peptide is a diluents just prior to adding to the wells of microplates coated with LCs (See page legend of figure 2, in particular). The reference peptide is useful for reducing the binding of the of immunoglobulin light chain to the Tamm and Horsfall protein or THP (See Table 1 mic, IC_{50} mM, in particular).

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

13. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
July 2, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600